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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,568	01/04/2002	Yasuhiko Shimizu	56871 (70958)	9246

21874 7590 09/22/2003

EDWARDS & ANGELL, LLP
P.O. BOX 9169
BOSTON, MA 02209

EXAMINER

LANDREM, KAMRIN R

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 09/22/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/030,568

Applicant(s)

SHIMIZU, YASUHIKO

Examiner

Kamrin R. Landrem

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,5 are rejected under 35 U.S.C. 102(b) as being anticipated by Hansson et al (USPN 5,656,605).

With reference to Figure 1, Hansson discloses a polyglycolic acid (2:53-55) artificial tube 2 having a lumen containing fibrous collagen (3:17-22) bodies 6 made of laminin (2:21-23) and other various growth factors (2:56-58).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hansson in view of Buscemi et al (USPN 5,769,883).

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Hansson, as discussed above, discloses the artificial nerve tube as claimed however Hansson fails to disclose the coating and pore size of the mesh. Buscemi teaches a biodegradable tubular body composed of polyglycolic acid, collagen (6:13) and laminin (3:49) having a collagen based inner and outer coating (6:24-33) and a pore size of 0.1-30 microns (6:66-67) that provides mechanical support and a uniform release of drugs to the surrounding area. Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the nerve tube as disclosed by Hansson to incorporate the coating and pore size of the tubular structure as taught by Buscemi in order to provide an artificial nerve tube that is bioabsorbable has improved biocompatible properties due to the coating.

Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hansson in view of Silver et al (USPN 4,703,108).

Hansson, as discussed above, discloses the artificial nerve tube as claimed however Hansson fails to disclose the method of producing the tube. Silver teaches the method for producing a biodegradable matrix comprising the steps of introducing a hydrochloric acid to dissolve the laminin coated (8:45-50) collagen, freezing the solution before freeze drying the solution (7:60-68) and then further crosslinked (9:9-16) to provide a controlled release to internal wounds requiring that only one surgery be performed. Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have composed the nerve tissue by the method as taught by Silver in order to produce a biodegradable matrix that allows for controlled release of drugs, growth factors, etc. and only requires one surgery.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1,4,5, and 6 of U.S. Patent No. 6,090,117. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims describe the structure of an artificial nerve tube made from a bioabsorbable mesh having a collagenous coating and fibrous collagen bodies filled with laminin.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kamrin R. Landrem whose telephone number is 703-305-8061. The examiner can normally be reached on 8:00-5:00, Monday-Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Kamrin Landrem
Examiner
AU 3738

KRL



CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700